

REMARKS

This response is submitted in reply to the Office Action mailed March 17, 2008 ("the Action"). Claims 1-29 and 34-73 are pending in the application.

I. The §112, First Paragraph Rejections

The Action rejects Claims 1-7, 9, 13-26, 28, 29, 34-42, 48-52, 56-69 and 71-73 as failing to comply with the written description requirements. The Examiner agrees with Applicant that some of the originally disclosed embodiments involve a single solid (elastomeric) material that has been "frozen and thawed several times until a solid device is formed with the desired mechanical properties" (Action, p. 2). The Action goes on to note that Claim 1 must be interpreted in light of other claims or "otherwise Applicant would have canceled Claims 12, 16, 23, 24, 27, 29, 39 and others." (Action, p. 2).

The Action goes on to provide a thoughtful summary of the issue with the current claim terminology of the "devoid of internal reinforcing material" and the "devoid of rigid endplate" negative limitations.

Applicant has amended the above claims to remove the negative *provisios*. As the Examiner has noted, the application does provide support for an implant formed of a single solid elastomeric material. Thus, Applicant has amended the claims as stated below to recite the novel implant configuration in a more positive manner that Applicant submits has support in the application.

1. (Currently Amended) An implantable prosthesis of shape generally similar to that of a spinal intervertebral disc ~~devoid of internal reinforcing material and rigid endplates and being a single non-articulating body~~ [[,]] comprised of only a single solid biocompatible elastomer with an ultimate strength in tension greater than about 100 kiloPascals, that exhibits the flexibility to allow at least 10 degrees of rotation between the top and bottom faces with torsions of at least 1 N-m without failing, wherein the single body optionally defines an exposed surface that is modified to provide specific surface characteristics.

34. (Currently Amended) An implantable non-articulating total disc replacement spinal disc, having a single non-articulating body with having

a superior surface and an inferior surface joined by a circumferential surface, the body defined by only a single solid biocompatible freeze-thaw hydrogel devoid of internal reinforcement material inside the disc body with an ultimate strength in tension greater than about 100 kiloPascals that exhibits the flexibility to allow at least 2 degrees of rotation between the superior and inferior faces with torsions of at least 0.01 N-m without failing, wherein the single body optionally defines an exposed surface that is modified to provide specific surface characteristics.

43. (Currently Amended) An implantable spinal total disc replacement body consisting essentially of only:

(a) a biocompatible solid polyvinyl alcohol (PVA) cryogel, the body being a single non-articulating body having an ultimate strength in tension greater than about 100 kiloPascals and sufficient elasticity to allow for shock absorption and flexibility of motion between adjacent vertebrae that allows at least 10 degrees of rotation between the top and bottom faces with torsions of at least 1 N-m without failing[,]); and

(b) an attachment extension band member at least partially surrounding an outer circumferential surface of the implantable spinal disc body,

wherein the body is shaped to have:

a substantially concave superior surface having a substantially flat periphery surface;

a substantially convex inferior surface having substantially flat periphery;

the superior and inferior surfaces being joined by a circumferential surface; and

the implantable spinal disc body being further characterized as being of a kidney shape formed by an extended oval surface and an indented portion, having a substantially rectangular cross-section, and having an anterior portion of greater thickness than a posterior portion.

63. (Currently Amended) A spinal total disc replacement prosthesis having a solid single body consisting essentially of only a freeze-thaw PVA cryogel that defines a core and annulus with mesh fabric moldably attached to only an exposed surface of the solid body to define fixation appendages adapted to attach to local vertebrae, wherein the core is devoid of internal reinforcing material, and wherein the prosthesis is non-articulating and has an ultimate tensile strength that is greater than 100 kiloPascals, and wherein the single body is configured to contact local vertebrae.

Applicant respectfully submits that the claims recite the configurations in a positive manner and are supported by the specification and figures. The claims also define over the prior art. The amendment to Claim 1 incorporates the subject matter of Claim 13, *e.g.*, the device includes surface modifications as provided in the original claims. That is, the device is a single solid body with exposed surface that is modified as originally recited in Claim 13, the exposed surface modification can include a number of features as provided in the original dependent claims. Original Claim 39 also recited that the body is at least partially surrounded by an attachment extension member (amended above to clarify that the outer surface of the body includes this member, *see, e.g.*, Figure 4).

Applicant respectfully submits that the above amendments address the Examiner's concerns regarding the use of the phrase "devoid of internal reinforcing material". Further, Applicant has canceled Claim 12 to clarify that the solid body does not include the internal component. Applicant has not canceled Claims 16, 23, 24, 27 and others but believes that the above amendments clarify the claimed invention, are supported by the application and define over the prior art.

As noted in a prior response, U.S. Patent No. 7,066,906 to Dickman requires the use of a nuclear core with a matrix of fabric. The core is well inside the implant, such a material would not be a surface modification nor exposed. The Dickman device requires that the core include the internal matrix for reinforcement, shearing and stress (*See, Abstract of Dickman*).

Applicant submits that the pending claims are supported by the specification (and at least by original presentation of the claims), that they include the use of surface modifications (*e.g.*, a fabric ring or attachment features), and that they also are patentable over the device of Dickman as they include only a single solid body of a single material (*e.g.*, no internal reinforcing core matrix as required by Dickman).

Applicant respectfully directs the Examiner's attention to the discussion of the prior art as presented in the Amendment filed 3/16/2007.

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CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. The Examiner is encouraged to telephone the undersigned at 919-854-1400 for resolution of any outstanding issues.

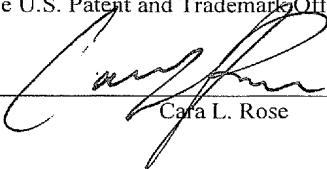
Respectfully submitted,


Julie H. Richardson
Registration No. 40,142

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on June 5, 2008.

Signature: 
Cara L. Rose